

**Notice of Allowability**

Application No.	Applicant(s)	
09/870,122	CLEARY ET AL.	
Examiner	Art Unit	
S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS**. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Applicants' amendment filed 09/13/04.
2.  The allowed claim(s) is/are 60-62, 64-66, 68, 69, 71-78 and 99, renumbered as claims 1-3, 4-6, 7, 8, 9-16 and 17 respectively.
3.  The drawings filed on 30 May 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\* c)  None of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 9/13/04
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other Attachment.

## **ATTACHMENT TO NOTICE OF ALLOWABILITY**

### **Applicants' Amendment**

- 1)** Acknowledgment is made of Applicants' amendment filed 09/13/04 in response to the non-final Office Action mailed 03/09/04. With this, Applicants have amended the specification.

### **Examiner's Amendment**

- 2)** An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Ann Viksnins in a telephonic interview on 23 November 2004.

This application has been amended as indicated below:

(a) In line 2 of claim 60, the limitation: 'Streptococcal C5a peptidase (SCP) peptide' is replaced with --peptide of Streptococcal C5a peptidase (SCP)--.

(b) In line 3 of claim 60, the recitation 'SCP.' is replaced with --the SCP, which elicits antibodies that neutralize the peptidase activity of wild-type SCP--.

(c) In line 3 of claim 61, the limitation 'wild-type SCP' is replaced with --the wild-type SCP--.

(d) In line 2 of claim 62, the limitation 'encoding SCP' has been deleted.

(e) In line 2 of claims 65 and 68, the limitation 'about' has been deleted.

(f) Claims 28-59, 70, 79-98 and 100 have been canceled.

(g) In the last two lines of claims 65, 66, 69 and 71, the limitations: 'wherein amino acid numbering of the peptide is consistent with numbering of a full-length SCP that includes a signal sequence' are replaced with the limitations: --wherein the position of the amino acid residues in the peptide corresponds to the position of amino acid residues in the wild-type SCP--.

(h) In line 1 of claim 71, the limitations: 'claim 70, wherein the SCP is a variant of wild-type SCP in that the variant SCP has' are replaced with the limitations: --claim 60, wherein the peptide has--.

(i) In line 1 of claims 75 and 76, the limitation 'native' is replaced with the limitation: --the wild-type--.

(j) In line 1 of claim 78, the limitation: 'Streptococcus is' is replaced with --SCP is

from--.

(k) Claim 73 has been amended as shown below:

--73. (Currently amended) The peptide of claim 60 71, wherein the SCP peptide is SCPA49D130A, SCPA49H193A, SCPA49N295A, SCPA49S512A, SCPA1D130A, SCPA1H193A, SCPA1N295A, SCPA1S512A, SCPBD130A, SCPBH193A, SCPBN295A, SCPBS512A or  $\Delta$ SCPA49.--

(l) Claim 74 has been amended as shown below:

--74. (Currently amended) The peptide of claim 73, wherein the SCP peptide is SCPA1S512A--.

(m) In line 1 of claim 99, the limitation ‘SCP’ is replaced with --peptide--.

#### **Status of Claims**

- 3) New claims 99 and 100 have been added via the amendment filed 09/13/04. Claims 60, 61, 64-66, 68-71 and 77 have been amended via the amendment filed 09/13/04. Claims 63 and 67 have been canceled via the amendment filed 09/13/04. Claims 28-59, 70, 79-98 and 100 have been canceled via this Examiner’s amendment. Upon further consideration, the product claims 73 and 74 have been rejoined with the elected claims. The restriction requirement that separated these claims from the elected invention is hereby withdrawn. Claims 60-62, 65, 66, 68, 69, 71, 73-76, 78 and 99 have been amended via this Examiner’s amendment. Claims 60-62, 64-66, 68, 69, 71-78 and 99 are pending and are under examination.

#### **Terminal Disclaimers**

- 4) Acknowledgment is made of Applicants’ terminal disclaimers filed 09/13/04 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patents 6,270,775 and 5,846,547.

#### **The Olmsted Declaration**

- 5) Acknowledgment is made of Applicants’ submission of the Olmsted Declaration filed under 37 CFR 1.132, which has been fully considered. The Declaration provides evidence that a streptococcal SCP peptide having more than one amino acid substitution at amino acid positions 130 and 512 does remain protective as tested in an animal model.

**Objection(s) Withdrawn**

6) The objection to the specification made in paragraph 8 of the Office Action mailed 03/09/04 is withdrawn in light of Applicants' amendments to the specification.

**Rejection(s) Moot**

7) The rejection of claims 63 and 67 made in paragraph 10 of the Office Action mailed 03/09/04 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 22 and 28 of Cleary (US 6,270,775) ('775) is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 63 and 67 made in paragraph 14(a) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 63 and 67 made in paragraph 19 of the Office Action mailed 03/09/04 under 35 U.S.C. § 102(b) as being anticipated by Wexler *et al.* (*PNAS* 82: 8144-8148, 1985 – Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 70 made in paragraph 12 of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 70 made in paragraph 14(a) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

12) The rejection of claim 70 made in paragraph 14(g) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

**Rejection(s) Withdrawn**

13) The rejection of claims 60-62, 68, 77 and 78 made in paragraph 10 of the Office Action mailed 03/09/04 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 22 and 28 of Cleary (US 6,270,775) ('775) is withdrawn in light of Applicants' terminal disclaimer disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,279,775.

14) The rejection of claims 60, 61, 77 and 78 made in paragraph 11 of the Office Action mailed

03/09/04 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Cleary (US 5,846,547 – Applicants' IDS) ('547) is withdrawn in light of Applicants' terminal disclaimer disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 5,846,547.

**15)** The rejection of claims 69, 71 and 72 made in paragraph 12 of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of the amendments to the base claim made via this Examiner's amendment.

**16)** The rejection of claims 60-62, 64, 65, 68, 71 and 75-78 made in paragraph 14(a) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**17)** The rejection of claim 61 made in paragraph 14(b) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**18)** The rejection of claim 61 made in paragraph 14(c) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**19)** The rejection of claims 65 and 66 made in paragraph 14(d) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**20)** The rejection of claim 65 made in paragraph 14(e) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**21)** The rejection of claims 65, 66, 68 and 69 made in paragraph 14(f) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**22)** The rejection of claims 65, 66, 68, 69, 71 and 72 made in paragraph 14(g) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**23)** The rejection of claim 60 made in paragraph 14(h) of the Office Action mailed 03/09/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants'

amendment to the claim.

- 24) The rejection of claims 60, 77 and 78 made in paragraph 16 of the Office Action mailed 03/09/04 under 35 U.S.C. 102(f) is withdrawn in light of Applicants' amendment to claim 60.
- 25) The rejection of claim 60 made in paragraph 16 of the Office Action mailed 03/09/04 under 35 U.S.C. § 102(b) as being anticipated by Cleary *et al.* (US 4,772,584 – Applicants' IDS) ('584) is withdrawn in light of Applicants' amendment to the claim.
- 26) The rejection of claims 60-62 and 75-78 made in paragraph 18 of the Office Action mailed 03/09/04 under 35 U.S.C. § 102(e) as being anticipated by Green *et al.* (US 6,100,380, filed 06/07/1995) as evidenced by *The Concise Encyclopedia: Biochemistry and Molecular Biology* (Third Edition, (Ed) Scott TA *et al.*, Walter de Gruyter, New York, p. 489, 1997), is withdrawn in light of Applicants' amendments to claim 60.
- 27) The rejection of claims 60-62, 64-66, 68 and 69 made in paragraph 19 of the Office Action mailed 03/09/04 under 35 U.S.C. § 102(b) as being anticipated by Wexler *et al.* (PNAS 82: 8144-8148, 1985 – Applicants' IDS), is withdrawn in light of Applicants' amendments to claim 60.

#### Remarks

- 28) Claims 60-62, 64-66, 68, 69, 71-78 and 99, now renumbered as claims 1-3, 4-6, 7, 8, 9-16 and 17 respectively are allowed.

The descriptive support for the limitations added via this Examiner's amendment to claim 60 can be found in the first paragraph of page 14 and lines 23-24 of page 34 of the specification. The amendments made to claims 65, 66, 68, 69 and 71 are supported at page 7, lines 15-28; page 10 line 3 to page 11, line 20; Examples 1 and 4-6; and Figures 1 and 2.

- 29) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.

- 30) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

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see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**31)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

November, 2004

S. DEVI, PH.D.  
PRIMARY EXAMINER

12/10/2004 11:48 FAX 612 288 9696

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Attorney's Docket No.: 09531-166002  
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Number of pages including this page    6 pages

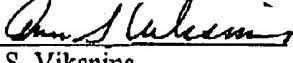
Applicant : Paul Patrick Cleary et al.                      Art Unit : 1645  
Serial No. : 09/870,122                                      Examiner : S. Devi  
Filed : May 30, 2001

Title : STREPTOCOCCAL C5a PEPTIDASE VACCINE

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Attached to this facsimile communication cover sheet is Supplemental Reply, faxed this  
10<sup>th</sup> day of December, 2004, to the United States Patent and Trademark Office.

Respectfully submitted,

  
Ann S. Viksnins

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